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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,872	09/30/2005	Akihiro Ohashi	20570/0203313-US0	2013
7278	7590	04/29/2008	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			TAYLOR II, JAMES W	
			ART UNIT	PAPER NUMBER
			4171	
			MAIL DATE	
			04/29/2008	PAPER
			DELIVERY MODE	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,872	OHASHI ET AL.	
	Examiner	Art Unit	
	James W. Taylor, II	4171	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/30/2008; 3/20/2006; 7/20/2006</u> . | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Polylactic acid resin articles comprising sodium oxide coated metal-hydroxide particles.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for metal oxide fillers, does not reasonably provide enablement for sodium oxide coated metal-oxide fillers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). See MPEP 2164.08.

The In re Wands, decision by the Federal Circuit sets forth a number of factors to weigh in considering compliance with the enablement requirement as follows:

1. the quantity of experimentation necessary;
2. the amount of direction or guidance presented;
3. the presence or absence of working examples;
4. the nature of the invention;
5. the state of the prior art;
6. the relative skill of those in that art;
7. the predictability or unpredictability of the art; and,
8. the breadth of the claims.

The applicant claims metal hydroxide filler with less than 0.1% (by mass of the filler) Na₂O present on the surface in a polylactic acid matrix. However, the applicant fails to teach a method for making a Na₂O coated metal hydroxide particle. Given that the applicant doesn't explain how to make the coated particle and that the prior art as a whole doesn't explain how to coat the particle, it is exceedingly difficult to practice the invention. One would be relegated to "trial and error," and this constitutes undue experimentation.

The Na₂O coating on the metal hydroxide particle is outside the scope of the applicant's aforementioned claims and is, ergo, rendering the claims non enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, 2nd paragraph, for failing to distinctly point out the meets and bounds of the claim.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “aromatic-aliphatic” is used by the claim to mean “synthesized from both aromatic and aliphatic monomers.” There is no general accepted meaning as the terms “aliphatic” and “aromatic” are mutually exclusive. In other words, the term “aromatic-aliphatic” is an oxymoron. Although the applicant gives examples of “aromatic-aliphatic” polyesters, the term is indefinite because the specification does not clearly define the term. The applicants need to make it clear that what meant is “aromatic aliphatic polyester copolymer”

The examiner will treat the rest of the office action assuming the applicant meant “synthesized from both aromatic and aliphatic monomers” by “aromatic-aliphatic.”

Claim 5 is rejected under 35 U.S.C. 112, 2nd paragraph, for failing to distinctly point out the meets and bounds of the claim. Claim 5 claims the limitation "has a degradation rate of 10% or less". However, a rate (by definition) is a measure of change as a function of time. Explanatively, a degradation rate of 10% per year is very

different than a degradation rate of 10% per day. Hence, the claim fails to distinctly point out of meets and the bounds of the claim.

Given the nature of this rejection, claim 5 cannot be treated for prior art rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimatzu Corp. (JP 2002-105298 A).

The applicant claims:

- (a) a lactic acid resin (Shimatzu, par. 1) and
- (b) a metal hydroxide (Shimatzu, par. 12) present at 15-40 parts by mass per 100 mass parts of component (a) (corresponding to 1-30%, Shimatzu, par. 12).

The examiner notes that although the applicant claims less than 0.1% by mass of Na₂O on the surface of the metal hydroxide, this includes 0%. Hence, the claim doesn't necessitate the presence of any Na₂O.

Regarding claim 3, the applicant further claims an inorganic filler, present at 1-20 mass parts per 100 mass parts of component (a) (corresponding to calcium carbonate, Shimatzu, para. 12).

Regarding claim 4, the applicant further claims the metal hydroxide is surface treated with:

- (c) a higher fatty acid,
- (d) silane coupling agent (corresponding to "beta-(3,4 epoxycyclohexyl) ethyltrimethoxysilane," Shimatzu, par. 13),
- (e) nitrate,
- (f) a titanate coupling agent,
- (g) sol-gel,
- (h) silicone polymer,
- (i) or resin.

The examiner notes that surface-treatment (i) will inherently be met by the polylactic acid *in vitro*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 103(a) as being unpatentable over Shimatzu, as applied to claim 1 and 3-4 above.

The applicant further claims:

(c) 20 to 80 mass parts of:

- (i) an aliphatic polyester (corresponding to "polybutylene succinate" or "P2," Shimatzu, par. 25 and 28) or
- (ii) a polyester synthesized from both aromatic and aliphatic monomers.

Shimatzu discloses (par. 28) roughly 14.3 mass parts by 100 mass parts of polylactide.

Shimatzu fails to teach the range of aromatic polyester that the applicant claims.

However, Shimatzu states (para. 3) that blending non polylactide aliphatic polyester into a polylactide formulation is known to create a product "excellent in shock resistance." The applicant has added aliphatic polyester to applicant's formulation to optimize a known effect. The courts have held that "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105, USPQ 223, 235 (CCPA 1955). See MPEP § 2144.05 (II) (A).

Thus, it would have been obvious at the time of invention or someone of ordinary skill in the art to change the amount of aliphatic polyester to optimize the known effect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Taylor, II whose telephone number is (571)270-5457. The examiner can normally be reached on 7:30 am to 5:00 pm (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 4171

James W Taylor, II
Examiner
Art Unit 4171

jwt2

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